Section 5 - 510(k) Summary

K063276

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter information

Contact person: Noor Malki
Manager, Regulatory Affairs & Compliance

Address: Bayer HealthCare, LLC
Diagnostic Division
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Norwood, MA 02062

DEC 2 8 2006

Phone: 781-269-3401

Date summary prepared: October 26, 2006

Device Information

Proprietary Name: Bayer CLINITEK Advantus™

Common name: Urine Chemistry Analyzer

Main classification name: Automated Urinalysis System

Main classification number: 21 CFR 862.2900, Class I

Main classification panel: Clinical Chemistry and Clinical Toxicology

Predicate Devices

Element	Predicate I	Predicate II
Device Name	CLINITEK 500	CLINITEK 200+
Common name	Urine Chemistry Analyzer	Urine Chemistry Analyzer
510(k) Number	CLINITEK family internal filing	K926359
Manufacturer	Bayer HealthCare, LLC	Heraeus Kulzer, Inc.

Device Description

The CLINITEK Advantus™ Urinalysis analyzer is a semi-automated, bench top analyzer. It is designed to read Bayer® Reagent Strips for Urinalysis, such as, MULTISTIX® 10 SG and Bayer MULTISTIX PRO® Reagent Strips.

The analyzer is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units. The analyzer can determine and report the color of the urine.

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All testing takes place on the fixed platform. The fixed platform consists of 3 sections: the strip loading station, the incubation/read station, and the waste bin. Strips are placed on the strip loading station. The push bar moves the strips to the incubation/read station, where they are tested. When testing is complete, the strips drop into the waste bin. When testing is complete, an internal thermal printer prints the test results.

Statement of Intended Use

The CLINITEK Advantus™ Urinalysis analyzer is a semi-automated, bench top analyzer. It is designed to read Bayer® Reagent Strips for Urinalysis, such as, MULTISTIX® 10 SG and MULTISTIX PRO® Reagent Strips.

This analyzer is intended for the measurement of the following: Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Specific Gravity, and Urobilinogen.

Tests performed using the CLINITEK Advantus™ are intended for in vitro diagnostic use.

Summary of Technological Characteristics

The analyzer utilizes system optics, push bar mechanics, measurement engine, barcode reading system, and is designed to preserve reagent algorithms and performance parameters.

Interaction with the CLINITEK Advantus™ analyzer is via an integrated touch screen. The analyzer features a color touch screen, ability for microscopic data entry, improved communications to LIS/HIS systems, input of load list, improved system QC, easy switching between traditional urine strips and newer strips, such as MULTISTIX PRO. The User is not required to make any calculations. Calibration is performed automatically each time a reagent strip is analyzed.

Assessment of Performance

Studies were conducted as internal laboratory setting and in clinical settings to demonstrate the performance of the CLINITEK Advantus™ analyzer and assess its substantial equivalence against the predicate devices and where applicable the referenced laboratory methods. In addition information on Software Development Life Cycle including software requirements specifications, device hazard analysis, and overall verification and validation activities were included to provide additional assurance of device performance.

Conclusion

In conclusion, these studies demonstrate that the CLINITEK Advantus is similar to both predicates in both Technological Characteristics and Intended Use. The data presented is a summary of external clinical evaluation, internal laboratory evaluation, and software development information. This information provides assurance that the CLINITEK Advantus™ is substantially equivalent to the currently marketed CLINITEK 500 and CLINTIEK 200+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Noor Malki
Manager, Regulatory Affairs & Compliance
Bayer HealthCare, LLC
Diagnostic Division
2 Edgewater Drive
Norwood, MA 02062

DEC 2 8 2006

Re: k063276
Trade/Device Name: Bayer CLINITEK Advantus™
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, JFY, JJB, JIN, LJX, JMT, CEN, JIR, JRE, CDM, KQO
Dated: October 26, 2006
Received: October 30, 2006

Dear Ms. Malki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063276

Device Name: CLINITEK Advantus™

Indications For Use:

The CLINITEK Advantus™ Urinalysis analyzer is a semi-automated, benchtop analyzer. It is designed to read Bayer® Reagent Strips for Urinalysis, such as, MULTISTIX® 10 SG and MULTISTIX PRO® Reagent Strips.

This analyzer is intended for the measurement of the following: Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Specific Gravity, and Urobilinogen. These measurements are used to assist diagnosis in the following areas:

- Kidney Function
- Urinary tract infections
- Metabolic disorders (e.g. diabetes mellitus)
- Liver Function

Tests performed using the CLINITEK Advantus™ are intended for in vitro diagnostic use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 1-2-96) K063276